Remarks

This invention is directed to effervescent compositions. Effervescent compositions are most often prepared using two dry ingredients that react in the presence of water to liberate CO_2 gas, usually via an acid-base interaction. A continuing problem with effervescent compositions is that the components usually employed to create the effervescence, a carbonate or bicarbonate and an edible organic acid (called the "effervescent couple"), can react before use by coming into contact in the presence of environmental humidity, condensation, or other conditions that expose the effervescent couple to water. Another problem is that certain medicines delivered via effervescent compositions, such as aspirin, can be vulnerable to degradation by one or both members of the effervescent couple. These problems can be particularly acute in effervescent tablets, because the compression step usually associated with tablet formation forces the members of an effervescent couple and the medicine into very close proximity. In humid environments and other damp conditions, the problems can become particularly acute.

Applicants have discovered that the stability of effervescent couples and the medicine delivered with an effervescent couple can be improved. Compositions in accordance with the invention are prepared by incorporating at least one member of the effervescent couple in a dispersion of a fusible sugar, sugar alcohol or sugar substitute. This dispersion is, however, more than a simple blending of powdered materials. As noted in the application, page 1, lines 35-37 and page 2, lines 12-15, stability is increased when one member of an effervescent couple is dispersed in a *melted* sugar, sugar alcohol or sugar substitute.

The new Examiner has issued a number of rejections to the claims. The claims had been amended several times in proceedings before the previous Examiner assigned to this case. Applicant has amended some of the claims under Section 112 and added claims 16 - 19. In light of these amendments and additions, applicant wishes to clarify some of the previous arguments made in this application.

The Examiner first rejected claims 8-10 under the written description requirement of 35 U.S.C. § 112. The Examiner asserts that the words "substantially throughout" and "substantial constituent" constitute new matter. The claims have been amended to remove the contested language, but applicant also traverses this rejection in light of the newly amended claims. The claimed composition "comprises" the claimed elements, including a structure formed by melting the ingredient and dispersing the CO_2 donor or said acidic component (or both) in the melt and resolidifying. Thus, for example, the composition of claim 8 may further comprise additional ingredients, such as a CO_2 donor or acidic component that are not melted and additional CO_2 donors and acidic components that are not dispersed in the melt. Accordingly, elimination of these terms does not narrow the scope of the claim.

Claim 8 and claim 11 have been amended to clarify that the stabilization is not limited to stabilization of the effervescent couple but also includes the pharmaceutical active.

The Examiner rejected claims 11-15 under Section 112 for "new matter" because claim 11 contained the term "substantially dispersed." Applicant has removed the word "substantial" from claim 11, but traverses this rejection for the same reason as it traverses

the rejection of claims 8-10. Amended claim 11 uses the open-ended term "comprises," which does not exclude the presence of "undispersed" materials.

The Examiner rejected claims 12 and 13 for using the term "ancillary substance" without antecedent basis. This error has been corrected.

The Examiner rejected claim 8 under 35 U.S.C. § 102 and § 103 over U.S. Patent No. 3,872,227 to Hoff et al.

Hoff is directed to techniques for taste masking penicillin and reports that there are four basic approaches to taste masking: (a) balancing a bitter taste with salty, sweet and acid tastes; (b) increasing the viscosity of the bitter material, thereby limiting the exposure of the material to the taste buds during consumption; (c) coating the bitter material; and (d) adding sweeteners to the bitter material. (Col. 1, l. 53 – Col. 2, l. 37) Hoff then discloses that the addition of an amino acid or amino acid salt helps to mask the bitter taste of penicillin, presumably by balancing the flavors in the overall formulation. One skilled in the art would recognize that techniques (a) and (d) only require loose association of the bitter material with the taste masking agent, while techniques (b) and (c) require more intimate interaction between the bitter material and the materials coating the bitter material. One skilled in the art would also recognize that the amino acids and acid salts of Hoff are used to balance flavors, as in techniques (a) and (d) not coat the bitter material. Thus, in example 7, Hoff prepares ingredients by mixing, with no added heat. While an alcohol-based sodium saccharin solution is added, the sodium saccharin only comprises 0.2% by weight of the formulation. So even if this added alcohol solution were to have some effect on the structure of the materials

emerging from the fluidized bed of Hoff's example 7, it is not present in an amount sufficient to stabilize the effervescent couple or the active ingredient.

The Examiner relies on M.P.E.P. § 2113 for the proposition that the asserted reference reasonably appears "to be either identical with or only slightly different than a product claimed in a product-by-process claim." But, M.P.E.P. § 2113 does not permit the Examiner to take the position that a mere mixture of ingredients may serve to teach a dispersion of one substance into a melted form of another substance. The M.P.E.P is careful to point out that the structure implied by a process step should be considered when assessing the patentability of product-by-process claims over the prior art, "especially where . . . the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product." (Citing In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979).) In Garnero, the term "interbonded by interfusion" adequately limited the structure of the claimed composite because terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations.

Example 7 of Hoff only associates the flavor ingredients (as in techniques (a) and (d) of Hoff). Example 7, the only effervescent example, does not teach or suggest the more intimate structure of a structure formed by melting, dispersing and resolidifying (claim 8) or a partially molten blend (claim 11). No experimentation is required to recognize the difference in structure between example 7 of Hoff and the claimed invention, any more than experimentation is required to recognize the structural difference between frozen lemonade and a granulated, physical mixture of ice and sugar.

The Examiner also rejected the claims 8-10 under Sections 102 and 103 and claims 11-15 under Section 103 in light of GB Patent No. 2,307,857 to Leslie et al. ("Leslie"). The Examiner argued that Leslie teaches the use of a polyethylene glycol that softens or melts below 150° C. in an effervescent product. The Examiner pointed out example 3 of Leslie and noted that the formulation included saccharin, polyethylene glycol, an effervescent couple, and a pharmaceutical active. In example 3, the materials were first blended in a mixer and then heated to 60° C. The Examiner has taken the position that the mere presence of the ingredients, dispersed in a polyethylene glycol substrate which has saccharin or sodium saccharin as "a substantial constituent" anticipates claims 8-10 and that claims 11-15 are obvious because one skilled in the art would readily be able to derive the claimed invention from the mixing and hot-melt extrusion of Leslie.

Applicant respectfully traverses these rejections. Polyethylene glycol is not the "ingredient" of the claims and as such is irrelevant to an anticipation or obviousness analysis. Even though polyethylene glycol 6000 can melt or soften at about 60° C., neither saccharin nor sodium saccharin melts anywhere near 60° C. The attached MSDS sheets for saccharin and sodium saccharin were downloaded from the internet, and they indicate that saccharin melts at 229° C. and sodium saccharin decomposes at a temperature above about 200° C.

The structure resulting from Leslie's example 3 would, at best, be described as particles of the effervescent couple, the active, and the sodium saccharin floating around in a polyethylene glycol matrix. Neither the 495 mg of citric acid, nor the 581 mg of sodium hydrogen carbonate, nor even the 40.5 mg of sodium carbonate could reasonably

be described as being dispersed in 2.5 mg of solid sodium saccharin that has not been at least partially melted. There is simply nothing corresponding to melted saccharin in Leslie's example 3, so Leslie cannot anticipate any claim or render any claim obvious.

The Examiner has also rejected the claims under Section 102 and 103 over U.S. Patent No. 6,071,539 to Robinson et al. ("Robinson").

The Examiner argued that claims 8-10 were anticipated by Robinson because that patent teaches effervescent granules and hot-melt extrudable binders forming a eutectic mixture (solid solution) with the acidic agent and active agents. The Examiner cited the abstract, tables 1-4 and column 13, lines 43-45 of Robinson to support the rejection.

The Examiner also rejected claims 11-15 as obvious over Robinson because the process steps in the claims are asserted to differ only in the order in which they are carried out in Robinson.

Applicant respectfully traverses these rejections. Robinson is directed to the preparation of effervescent granules having a "controllable rate of effervescence" (Abstract). A mixture of the acidic component and the "hot-melt extrudable binder" form a "eutectic mixture" (Abstract). The hot-melt process used by Robinson allows for "extremely short exposure times of compounds to elevated temperatures" (Col. 3, l. 16-18). Tablets made in accordance with Robinson are prepared by first drying the materials at 40° C. overnight, preferably in a vacuum, then mixing the effervescent materials and the binder. This mixture is then hot-melt extruded as part of the process for making granules comprising the effervescent couple and the binder (Example 1). These granules are then formulated into effervescent compositions (Example 3 and Table 3) by mixing

with other ingredients (Example 4 and Example 6) or made into tablets using conventional techniques (Example 7). Mannitol, one of the ingredients listed in Example 3, is not subjected to hot-melt extrusion, and the only example to use aspirin (formulation E of Example 3) uses polyethylene glycol 4000 as the hot-melt extrusion binder.

Robinson provides no stability data, which is not surprising since Robinson is not directed to stability issues. As a result, Robinson cannot teach or suggest whether or not it has a "sufficient amount of said CO_2 donor or said acidic component . . . dispersed in said ingredient to stabilize at least one of said CO_2 donor, said acidic component, and said degradable pharmaceutically active substance." Any inference as to what is actually happening in Robinson must be based on inherency, and not on hindsight reconstruction. Inherency must be certain. "The fact that a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." M.P.E.P. § 2112 (emphasis added). The Robinson binder is not limited to the "ingredient" of the present claims, so the teaching of Robinson already fails the inherency test.

An analysis of the examples containing xylitol in Robinson shows that none of the examples rises to the same weight percentage as the examples tested in the present application. In the application, the lowest weight percentage tested had a weight percentage of 30% xylitol (example 3), while the highest weight percent in a Robinson example is about 28%, as shown in the table on the next page.

Wt Percent of Binder in Robinson Examples					
Example	Wt. % Acid	Wt. % Base	Wt. % Binder	Calculated Relative Wt% binder in granules of Acid + Base + binder	Wt. % Ratio of binder to co-extruded material
J	34	51	15	15.00%	0.18
K	40	50	10	10.00%	0.11
M	35	35	10	12.50%	0.14
N	37	38	8	9.64%	0.11
O	40	40	10	11.11%	0.13
P	40	40	3.5	4.19%	0.04
Q	35	35	13.5	16.17%	0.19
R	37	38	11.5	13.29%	0.15
S	40	40	13.5	14.44%	0.17
Table 4					
1	12	13	0	0.00%	0.00
2	12	13	0	0.00%	0.00
3	14	15	10	25.64%	0.34
4	15	18	0	0.00%	0.00
5	18	20	15	28.30%	0.39
6	13	15	10	26.32%	0.36

In contrast, all of the examples in the present application have a ratio of the weight percent of the "ingredient" to the weight percent of the materials dispersed therein of at least 0.4. Only Example 3 of the application has a ratio below 1.0. Thus, it cannot be said that Robinson teaches anything about stabilization. Nor can it be argued with certainty that Robinson has the structure of claims 8-10. The Robinson process cannot teach or suggest the process of claims 11-15, because there is no evidence suggesting that the effervescent material is dispersed in the "ingredient." Rather, Robinson urges short exposure times (col. 3, l. 16-18) at lower temperatures (col. 13, l. 39-46), and preferably

with polyethylene glycol (col. 5, l. 58-60), which is not one of the "ingredients" of the claimed invention.

None of the cited art addresses newly added claims 16 and 17, in which the active ingredient is aspirin. Aspirin is especially vulnerable to degradation, yet the only example in Robinson that uses aspirin also uses polyethylene glycol as the binder. The examples in Leslie disclose only Tramadol, and the Hoff examples use only penicillins.

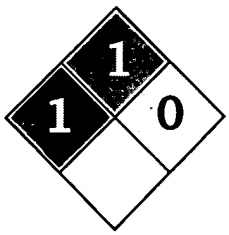
The claimed invention is not taught or suggested by the cited references, either alone or in combination. Hoff and Leslie are taste masking patents. Robinson is directed to controlling the rate of effervescence. Since none of the patents is concerned with the advantages of the claimed invention, it is not surprising that none of the patents teaches or suggests the claimed invention. Applicant has developed a unique structure and process for creating that unique structure. Applicant respectfully requests withdrawal of the rejections and allowance of the claims.

Respectfully Submitted,

Richard S. Bullitt
Reg. No. 30,733

Bayer HealthCare, LLC
36 Columbia Road
Morristown, NJ 07962

ScienceLab.com
Chemicals & Laboratory Equipment



Health	1
Fire	1
Reactivity	0
Personal Protection	E

Material Safety Data Sheet
Saccharin MSDS

Section 1: Chemical Product and Company Identification

Product Name: Saccharin

Catalog Codes: SLS4417, SLS2200

CAS#: 81-07-2

RTECS: DE4200000

TSCA: TSCA 8(b) inventory: Saccharin

CI#: Not available.

Synonym: 1,2-Benzisothiazol-3(2H)-one 1,1-dioxide

Chemical Formula: C7H5NO3S

Contact Information:

Sciencelab.com, Inc.
14025 Smith Rd.
Houston, Texas 77396

US Sales: **1-800-901-7247**
International Sales: **1-281-441-4400**

Order Online: ScienceLab.com

CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

For non-emergency assistance, call: 1-281-441-4400

Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
Saccharin	81-07-2	100

Toxicological Data on Ingredients: Not applicable.

Section 3: Hazards Identification

Potential Acute Health Effects:
Hazardous in case of ingestion. Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of inhalation.

Potential Chronic Health Effects:
CARCINOGENIC EFFECTS: Not available.
MUTAGENIC EFFECTS: Not available.
TERATOGENIC EFFECTS: Not available.
DEVELOPMENTAL TOXICITY: Not available.
Repeated or prolonged exposure is not known to aggravate medical condition.

Section 4: First Aid Measures

Eye Contact: Immediately flush eyes with running water for at least 15 minutes, keeping eyelids open. Cold water may be used.

Skin Contact:
After contact with skin, wash immediately with plenty of water. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases and groin. Cover the irritated skin with an emollient. If irritation persists, seek medical attention. Wash contaminated clothing before reusing.

Serious Skin Contact: Not available.

Inhalation: Allow the victim to rest in a well ventilated area. Seek immediate medical attention.

Serious Inhalation: Not available.

Ingestion:
Do not induce vomiting. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: Not available.

Flash Points: Not available.

Flammable Limits: Not available.

Products of Combustion: These products are carbon oxides (CO, CO2), nitrogen oxides (NO, NO2...).

Fire Hazards in Presence of Various Substances: Not available.

Explosion Hazards in Presence of Various Substances:
Risks of explosion of the product in presence of mechanical impact: Not available.
Risks of explosion of the product in presence of static discharge: Not available.

Fire Fighting Media and Instructions:
SMALL FIRE: Use DRY chemical powder.
LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: Not available.

Special Remarks on Explosion Hazards: Not available.

Section 6: Accidental Release Measures

Small Spill:
Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:
Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7: Handling and Storage

Precautions:

Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. If ingested, seek medical advice immediately and show the container or the label.

Storage:
Keep container dry. Keep in a cool place. Ground all equipment containing material. Keep container tightly closed. Keep in a cool, well-ventilated place. Combustible materials should be stored away from extreme heat and away from strong oxidizing agents.

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection: Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

Section 9: Physical and Chemical Properties

Physical state and appearance: Solid.

Odor: Not available.

Taste: Not available.

Molecular Weight: 183.18 g/mole

Color: Not available.

pH (1% soln/water): Not available.

Boiling Point: Decomposes.

Melting Point: 229°C (444.2°F)

Critical Temperature: Not available.

Specific Gravity: 0.828 (Water = 1)

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Ejt qf st jpo Qspqf sujf t ; Opubwbjrbcrh/

Tpmacjrjuz; W sz t rjhi uz t pmcrh jo dpra x buf s/

Tf dujpo 21; Tubcjrjuz boe Sf bdujwjuz Ebub

Tubcjrjuz; Ui f qspevdujt tubcrh/

Jbt ubcjrjuz Uf n qf sbuvsf ; Opubwbjrbcrh/

Dpoejujpot pgJbt ubcjrjuz; Opubwbjrbcrh/

Jbdpn qbujcjrjuz x jui wbsjpvt t vct ubodf t ; Opubwbjrbcrh/

Dpsspt jwjuz; Opo.dpsspt jwf jo qsf t f odf pghrbt t /

Tqf djbrSf n bsl t po Sf bdujwjuz; Opubwbjrbcrh/

Tqf djbrSf n bsl t po Dpsspt jwjuz; Opubwbjrbcrh/

Qprzn f sj{ bujpo; Op/

Tf dujpo 22; Upyjdprphjdbmbgpsn bujpo

Spvuf t pgFousz; Jbhf t ujpo/

Upyjdjuz up Bojn brh; Bdvuf psbmupyjdjuz)ME61*; 28111 n h0 h \Npvt f ^/

Di spojd Fggf dut po I vn bot ; Opubwbjrbcrh/

Pui f s Upyjd Fggf dut po I vn bot ;
I b{bsepvt jo dbt f pgjohf t ujpo/
Trjhi umz i b{bsepvt jo dbt f pgt I jo dpoubdu)jssjubou- pgjoi brbujpo/

Tqf djbrSf n bsl t po Upyjdjuz up Bojn brh; Opubwbjrbcrh/

Tqf djbrSf n bsl t po Di spojd Fggf dut po I vn bot ; Qbt t f t ui spvhi ui f qrbdf oubmcbssjf sjo bojn brh

Tqf djbrSf n bsl t po pui f s Upyjd Fggf dut po I vn bot ; Opubwbjrbcrh/

Tf dujpo 23; Fdprphjdbmbgpsn bujpo

Fdpupyjdjuz; Opubwbjrbcrh/

CPE6 boe DPE; Opubwbjrbcrh/

Qspevdut pgCjpef hsbebujpo;
Qpt t jcmz i b{bsepvt t i psuf sn ef hsbebujpo qspevdut bsf opurjlf mz/ I px f wf s- mpoh uf sn ef hsbebujpo qspevdut n bz bsjt f /

Upyjdjuz pgui f Qspevdut pgCjpef hsbebujpo; Ui f qspevdut pgef hsbebujpo bsf n psf upyjd/

Tqf djbrSf n bsl t po ui f Qspevdut pgCjpef hsbebujpo; Opubwbjrbcrh/

Tf dujpo 24; Ejt qpt bmDpot jef sbujpot

X bt uf Ejt qpt bm

Tf dujpo 25; Usbot qpsuJbgpsn bujpo

```
EPU Drtt t jgdbujpo; Opub EPU dpouspmfe n buf sjbm)Vojuf e Tubuf t*/

Jef oujgdbujpo; Opubqqrjdbcrfv/

Tqf djbmQspwjt jpot gps Usbot qpsu Opubqqrjdbcrfv/
```

Tf dujpo 26; Pui f s Sf hvrbupsz Jbgpsn bujpo

```
Gf ef sbmboe Tubuf Sf hvrbujpot ;
Dbrjgpsojb qspq/ 76; Ui jt qspevdudpoubjot ui f gpmpx joh johsf ejf out gps x i jdi ui f Tubuf pgDbrjgpsojb i bt gpvoe up
dbvt f dbodf s- cjsui ef gf dut ps pui f ssf qspevdujwf i bsn - x i jdi x pvmf sf r vjsf b x bsojoh voef s ui f tubuvuf ;
Tbddi bsjo
Dbrjgpsojb qspq/ 76; Ui jt qspevdudpoubjot ui f gpmpx joh johsf ejf out gps x i jdi ui f Tubuf pgDbrjgpsojb i bt gpvoe up
dbvt f dbodf s x i jdi x pvmf sf r vjsf b x bsojoh voef s ui f tubuvuf ; Tbddi bsjo
Qf oot zmbojb SUL; Tbddi bsjo
Nbt t bdi vt f ut SUL; Tbddi bsjo
UTDB 9)c* jowf oupsz; Tbddi bsjo
TBSB 424 upyjd di f n jdbnmopujgdbujpo boe sf rmbt f sf qpsujoh; Tbddi bsjo
DFSDMB; I b{bsepvt t vct ubodf t /; Tbddi bsjo

Pui f s Sf hvrbujpot ; Opubwbjmbcrfv//

Pui f s Drtt t jgdbujpot ;

X I NJT )Dbobeb*; Opudpouspmfe voef s X I NJT )Dbobeb*/

ETDM)FFD*;
Ui jt qspevdujt opudrtt t jgjf e bddpsejoh
up ui f FV sf hvrbujpot /

I NJT )V/T/B/*;

  I f bnj I b{bse; 2

  Gjsf I b{bse; 2

  Sf bdujwjuz; 1

  Qf st pobmQspuf dujpo; F

ObujpobmGjsf Qspuf dujpo Bt t pdjbujpo )V/T/B/*;

  I f bnj ; 2

  Gmbn n bcjmjuz; 2

  Sf bdujwjuz; 1

  Tqf djgjd i b{bse;

Qspuf dujwf Fr vjqn f ou
Hmpwf t /
Mbc dpbu/
Evt usf t qjsbups/ Cf t vsf up vt f bo
bqqspwf eQdf sujgf e sf t qjsbups ps
f r vjwbmfou/
Tbgf uz hmtt t f t /
```

Tf dujpo 27; Pui fs Jogpsn bujpo

Sf gf sf odf t ; Opubwbjmbcmf/

Pui f s Tqf djbmDpot jef sbujpot ; Opubwbjmbcmf/

Dsf buf e; 2101: 08116 17;34 QN

Mbt uVqebuf e; 22017 08119 23;11 QN

Ui f jogpsn bujpo bcpwf jt cf mjfwf e up cf bddvsbuf boe sf qsf t f out ui f cf t ujogpsn bujpo dvssf oumz bwbjmbcmf up vt/ I px f wf s- xf n bl f op xbssboumz pg n f sdi boubcjmjuz ps boz pui f s xbssbouz- f yqsf tt ps jn qmjf e- xju i sf t qf du up t vdi jogpsn bujpo- boe xf bt t vn f op mjbcjmjuz sf t vmujoh gspn jut vt f/ Vt f st t i pvme n bl f ui f js px o jowf t ujhbujpot up ef uf sn jof ui f t vjubcjmjuz pg ui f jogpsn bujpo gps ui f js qbsujdvmbs qvsqpt f t / Jo op f wf out i bmmTdjf odf Mbc/dpn cf mjbcmf gps boz dmbjn t - mpt t f t - ps ebn bhf t pg boz ui jse qbsuz ps gps mpt uqspgjut ps boz t qf djbmjoejsf du- jodjef oubmdpot f r vf oujbmps f yf n qmbsz ebn bhf t - i px t pf wf s bsjt joh- f wf o jg Tdjf odf Mbc/dpn i bt cf f o bewjt f e pg ui f qpt t jcjmjuz pg t vdi ebn bhf t /

MSDS Number: **S0073** * * * * * *Effective Date:* ***02/10/09*** * * * * * *Supercedes:* ***05/23/06***

MSDS Material Safety Data Sheet

From: Mallinckrodt Baker, Inc.
222 Red School Lane
Phillipsburg, NJ 08865

Mallinckrodt CHEMICALS J.T.Baker

24 Hour Emergency Telephone: 908-859-2151
CHEMTREC: 1-800-424-9300

National Response in Canada
CANUTEC: 613-996-6666

Outside U.S. and Canada
Chemtrec: 703-527-3887

NOTE: CHEMTREC, CANUTEC and National Response Center emergency numbers to be used only in the event of chemical emergencies involving a spill, leak, fire, exposure or accident involving chemicals.

All non-emergency questions should be directed to Customer Service (1-800-582-2537) for assistance.

SACCHARIN SODIUM

1. Product Identification

Synonyms: 1,2-benzisothiazol-3(2H)-one,1,1-dioxide, sodium salt dihydrate; Sodium benzosulphimide
CAS No.: 128-44-9 (Anhydrous); 6155-57-3 (Dihydrate)
Molecular Weight: 241.19
Chemical Formula: C7H4NNaO3S.2H2O
Product Codes:
J.T. Baker: 3875
Mallinckrodt: 7260, 7264

2. Composition/Information on Ingredients

Ingredient	CAS No	Percent	Haza
Sodium Saccharin	128-44-9	94 - 95%	Y
Water	7732-18-5	5 - 6%	N

3. Hazards Identification

Emergency Overview

As part of good industrial and personal hygiene and safety procedure, avoid all unnecessary exposure to the chemical substance and ensure prompt removal from skin, eyes and clothing.

SAF-T-DATA(tm) Ratings (Provided here for your convenience)

Health Rating: 1 - Slight
Flammability Rating: 1 - Slight
Reactivity Rating: 0 - None
Contact Rating: 1 - Slight
Lab Protective Equip: GOGGLES; LAB COAT; PROPER GLOVES
Storage Color Code: Green (General Storage)

Potential Health Effects

Inhalation:
Nuisance dust, causing coughing and sneezing.
Ingestion:
Ingestion of 5g has been reported to cause nausea, vomiting and diarrhea. Small quantities are normally tolerated by the body and are eliminated almost quantitatively via the kidneys.
Skin Contact:
No adverse effects expected.
Eye Contact:
No adverse effects expected but dust may cause mechanical irritation.
Chronic Exposure:
No information found.
Aggravation of Pre-existing Conditions:
No information found.

---

4. First Aid Measures

Inhalation:
Not expected to require first aid measures. Remove to fresh air. Get medical attention for any breathing difficulty.
Ingestion:
Give several glasses of water to drink to dilute. If large amounts were swallowed, get medical advice.
Skin Contact:
Wash exposed area with soap and water. Get medical advice if irritation develops.
Eye Contact:

Wash thoroughly with running water. Get medical advice if irritation develops.

---

5. Fire Fighting Measures

Fire:
As with most organic solids, fire is possible at elevated temperatures or by contact with an ignition source.
Explosion:
Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Fire Extinguishing Media:
Water spray, dry chemical, alcohol foam, or carbon dioxide.
Special Information:
In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

---

6. Accidental Release Measures

Remove all sources of ignition. Ventilate area of leak or spill. Wear appropriate personal protective equipment as specified in Section 8. Spills: Clean up spills in a manner that does not disperse dust into the air. Use non-sparking tools and equipment. Reduce airborne dust and prevent scattering by moistening with water. Pick up spill for recovery or disposal and place in a closed container. Small amounts of residue may be flushed to sewer with plenty of water.

---

7. Handling and Storage

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage. Containers of this material may be hazardous when empty since they retain product residues (dust, solids); observe all warnings and precautions listed for the product. Avoid dust formation and control ignition sources. Employ grounding, venting and explosion relief provisions in accord with accepted engineering practices in any process capable of generating dust and/or static electricity. Empty only into inert or non-flammable atmosphere. Emptying contents into a non-inert atmosphere where flammable vapors may be present could cause a flash fire or explosion due to electrostatic discharge.

---

8. Exposure Controls/Personal Protection

Airborne Exposure Limits:
None established.
Ventilation System:
A system of local and/or general exhaust is recommended to keep employee exposures as low as possible. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, *Industrial Ventilation, A Manual of Recommended Practices*, most recent edition, for details.
Personal Respirators (NIOSH Approved):
For conditions of use where exposure to dust or mist is apparent and engineering controls are not feasible, a particulate respirator (NIOSH type N95 or better filters) may be worn. If oil particles (e.g. lubricants, cutting fluids, glycerine, etc.) are present, use a NIOSH type R or P filter. For emergencies or instances where the exposure levels are not known, use a full-face positive-pressure, air-supplied respirator. WARNING: Air-purifying respirators do not protect workers in oxygen-deficient atmospheres. Where respirators are required, you must have a written program covering the basic requirements in the OSHA respirator standard. These include training, fit testing, medical approval, cleaning, maintenance, cartridge change schedules, etc. See 29CFR1910.134 for details.
Skin Protection:
Wear protective gloves and clean body-covering clothing.
Eye Protection:
Safety glasses. Maintain eye wash fountain and quick-drench facilities in work area.

---

9. Physical and Chemical Properties

Appearance:
White crystals.
Odor:
Odorless.
Solubility:
80g in 100g of water.
Specific Gravity:
No information found.
pH:
Aqueous solution is neutral to slightly alkaline to litmus.
% Volatiles by volume @ 21C (70F):
0
Boiling Point:
Not applicable.
Melting Point:
> 200C (> 392F) Decomposes.
Vapor Density (Air=1):

No information found.
Vapor Pressure (mm Hg):
No information found.
Evaporation Rate (BuAc=1):
No information found.

---

10. Stability and Reactivity

Stability:
Stable under ordinary conditions of use and storage.
Hazardous Decomposition Products:
Burning may produce carbon monoxide, carbon dioxide, sulfur oxides, and nitrogen oxides.
Hazardous Polymerization:
Will not occur.
Incompatibilities:
Strong oxidizers.
Conditions to Avoid:
Heat, flame, ignition sources, dusting, moisture and incompatibles.

---

11. Toxicological Information

Oral rat LD50: 1280 mg/kg; investigated as a tumorigen, mutagen, reproductive effector.

--------\Cancer Lists\----------

Ingredient	---NTP Carcinogen--- Known	Anticipated	IARC Category
Sodium Saccharin (128-44-9)	No	No	None
Water (7732-18-5)	No	No	None

---

12. Ecological Information

Environmental Fate:
No information found.
Environmental Toxicity:
No information found.

---

13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

---

14. Transport Information

Not regulated.

---

15. Regulatory Information

--------\Chemical Inventory Status - Part 1\--------

Ingredient	TSCA	EC	Japan	Australia
Sodium Saccharin (128-44-9)	Yes	Yes	Yes	Yes
Water (7732-18-5)	Yes	Yes	Yes	Yes

--------\Chemical Inventory Status - Part 2\--------

Ingredient	Korea	--Canada-- DSL	NDSL	Phil.
Sodium Saccharin (128-44-9)	Yes	Yes	No	Yes
Water (7732-18-5)	Yes	Yes	No	Yes

--------\Federal, State & International Regulations - Part 1\--------

Ingredient	-SARA 302- RQ	TPQ	------SARA 313----- List	Chemical Catg
Sodium Saccharin (128-44-9)	No	No	No	No
Water (7732-18-5)	No	No	No	No

--------\Federal, State & International Regulations - Part 2\--------

Ingredient	CERCLA	-RCRA- 261.33	-TSCA- 8(d)
Sodium Saccharin (128-44-9)	No	U202	No
Water (7732-18-5)	No	No	No

Chemical Weapons Convention: No TSCA 12(b): No CDTA: No
SARA 311/312: Acute: Yes Chronic: No Fire: No Pressure: No
Reactivity: No (Mixture / Solid)

WARNING:
THIS PRODUCT CONTAINS A CHEMICAL(S) KNOWN TO THE STATE OF

CALIFORNIA TO CAUSE CANCER.

Australian Hazchem Code: None allocated.
Poison Schedule: None allocated.
WHMIS:
This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

---

16. Other Information

NFPA Ratings: Health: **0** Flammability: **1** Reactivity: **0**
Label Hazard Warning:
As part of good industrial and personal hygiene and safety procedure, avoid all unnecessary exposure to the chemical substance and ensure prompt removal from skin, eyes and clothing.
Label Precautions:
Not applicable.
Label First Aid:
Not applicable.
Product Use:
Laboratory Reagent.
Revision Information:
No Changes.
Disclaimer:
****

Mallinckrodt Baker, Inc. provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. MALLINCKRODT BAKER, INC. MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, MALLINCKRODT BAKER, INC. WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.

****

Prepared by: Environmental Health & Safety
Phone Number: (314) 654-1600 (U.S.A.)